

### **REMARKS**

Applicants wish to thank the Examiner for the review of the present application. Applicants have amended claim 1 and cancelled claims 2-5. Accordingly, claims 1, and 6-21 are currently pending in the application.

### **35 U.S.C. §102**

Claims 1-9, 10, and 12-13 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent 5,915,036 (Grunkin et al., hereinafter Grunkin).

Amended claim 1 defines, in relevant part, a method of predicting bone or articular disease that includes determining one or more micro-structural parameters, one or more macroanatomical parameters, and one or more biomechanical parameters of a joint. Once the parameters are determined, the method combines the parameters to predict the risk of bone or articular disease. The combined parameters include a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter.

Grunkin does not teach such a method. Instead, Grunkin discloses a method of estimating the bone quality of a vertebra using a two-dimensional image (col. 3, lines 25-30). In particular, Grunkin performs at least one of a variety of background correction techniques and manipulates the two-dimensional image to either enhance prominent features or reduce less dominant features (col. 4, lines 43-54). Grunkin then extracts information about the trabecular structure from the manipulated image and estimates the bone quality (col. 4, lines 55-60). Nowhere does Grunkin teach or suggest determining one or more micro-structural parameters, macroanatomical parameters, and biomechanical parameters in a joint and combining the parameters (including a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter) to predict the risk of bone or articular disease. Rather, Grunkin extracts the trabecular information and then introduces the information into an estimation procedure to estimate the bio-mechanical properties of the bone. In other words, bio-mechanical information is the end product of Grunkin's estimation procedure (col. 10, lines 25-30). This is in direct contrast to claim 1, which requires the micro-structural, macro-anatomical, and bio-mechanical parameters to be combined in order to predict the risk of bone or articular

disease. Grunkin merely uses one parameter (e.g., the trabecular information) to determine another (e.g., bio-mechanical information).

Although Grunkin suggests that other information (such as age, sex, species, race, the specific bone considered in the vertebrae, estimated Bone Mineral Density (BMD), and/or estimated Bone Mineral Content (BMC)) may be included in the estimation procedure, none of the other information can constitute either a macro-anatomical parameter or a bio-mechanical parameter. The term macro-anatomical parameter refers to those parameters that may be measured on the macro-scale (e.g., using a ruler). For example, parameters such as the overall geometry of the bone, the length of the neck, diameter of the femoral head, thickness of the cortical bone, etc. can be considered macro-anatomical parameters. The term biomechanical parameters refers information that may be obtained from such analyses as finite element modeling, for example. None of Grunkin's additional information can constitute either a macro-anatomical or biomechanical parameter.

Furthermore, the specification of the present application clearly identifies information such as bone mineral density as being separate from micro-structural, macro-anatomical, and bio-mechanical information. In particular, throughout the application, the specification states that "bone density, microarchitecture, macro-anatomical, and/or biomechanical" analyses can be done (for example, paragraphs 58 and 62 of the published application). These passages clearly indicate that the present invention classifies bone density as separate from the parameters required by claim 1. Moreover, even if information such as BMD is considered either a macro-anatomical or a biomechanical parameter, which, as described above, it cannot, Grunkin still would only combine two of three parameters required by claim 1.

The office action suggests that Grunkin teaches determining and combining the required parameters at column 10, lines 25-29. Applicants respectfully disagree. The cited passage describes how Grunkin uses its estimation procedure to estimate bio-mechanical properties of the bone. As described above, this passage is in direct contrast to claim 1. In particular, this passage describes using one parameter (e.g., a microstructural parameter) to estimate another (e.g., a biomechanical parameter), whereas

claim 1 requires determining and combining the parameters (e.g., a microstructural, macroanatomical, and biomechanical).

Therefore, since Grunkin fails to teach or suggest determining and combining the parameters required by claim 1 (e.g., micro-structural, macroanatomical, and biomechanical), claim 1 is allowable over Grunkin. Moreover, claims 6-10, 12, and 13, which depend from claim 1, are allowable for at least the same reasons.

35 U.S.C. §103(a)

Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Grunkin in view of U.S. Patent Number 6,442,287 (Jiang, hereinafter Jiang).

As a dependent claim of claim 1, claim 11 includes all of the limitations of independent claim 1, which is allowable over Grunkin as discussed above. Therefore, claim 11 is also allowable over Grunkin for at least the same reasons.

In addition, the disclosure of Jiang fails to satisfy the deficiencies of Grunkin. In particular, Jiang discloses a method for analyzing bone using digital images. Although Jiang discloses measuring and merging a variety of parameters, nowhere does Jiang teach or suggest combining a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter to predict bone and articular disease. Accordingly, Grunkin and Jiang fail to teach or suggest, alone or in combination, all of the limitations of claim 11. Therefore, claim 11 is allowable over the combination of Grunkin and Jiang.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,306,822 (Kumagai et al., hereinafter Kumagai) in view of Grunkin. As dependent claims of claim 1, claims 14-19 include all of the limitations of claim 1. Therefore, claims 14-19 are allowable over Grunkin for at least the same reasons as discussed above for claim 1.

In addition, Kumagai fails to satisfy the deficiencies of Grunkin. In particular, Kumagai teaches a phosphopeptide and a method of treating bone disease using the phosphopeptide. Kumagai fails to teach or suggest determining and combining the parameters required by the present claims. Accordingly, Grunkin and Kumagai fail to

teach or suggest, alone or in combination, all of the limitations of claims 14-19.

Therefore, claims 14-19 are allowable over the combination of Grunkin and Kumagai.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunkin. As dependent claims of claim 1, claims 20-21 include all of the limitations of claim 1. Accordingly, claims 20-21 are allowable over Grunkin for at least the same reasons as discussed above for claim 1.

The office action suggests that Grunkin does not specifically disclose the steps in which the parameters used are selected from the group consisting of total cartilage volume as claimed in claim 20 and from the group of a volume of bone marrow as claimed in claim 21. The office action further suggests that it would have been an obvious matter of design choice to modify the method of Grunkin by replacing the trabecular parameters to determine the strength of bone and this the likelihood of risk of fracture with information relating to the cartilage volume parameters and bone marrow volume parameters. However, even if this were true, Grunkin still fails to teach or suggest determining one or more micro-structural parameters, macroanatomical parameters, and biomechanical parameters in a joint and combining the parameters (including a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter) to predict the risk of bone or articular disease. Therefore, claims 20-21 are allowable over Grunkin for at least the same reasons as discussed above for claim 1.

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. Applicants believe that a three month extension of time is required and hereby request that the associated fees be charged to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972. Applicants also request that the examiner contact applicant's attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

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